



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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Richard Staack, Ph.D.
Senior Scientist
Cognis Corporation
5325 South Ninth Avenue
La Grange, IL 60525-3602

Dear Dr. Staack:

This is in response to your letter to the Food and Drug Administration (FDA) dated July 17, 2000. In your letter, you asked us to comment on changes to a claim you are making for the dietary ingredient Prevastein™, which is composed of soy isoflavones. Your letter responds to our letter dated June 13, 2000 about a submission you made pursuant to 21 U.S.C. 343(r)(6).

In our May 22, 2000 letter, we stated that the claim "In animal models that mimic women's postmenopausal years, studies by Arjmandi and colleagues have demonstrated that a diet containing isoflavones within soy helped maintain bone density" suggested that your product was intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B). We further stated that the product appeared to be subject to regulation under the drug provisions of the Act because the statements suggested that it was intended to treat, prevent, or mitigate disease, namely osteoporosis in post-menopausal women.

In your current letter, you propose to modify the claim by changing the term "density" to "health." FDA has considered the proposed revision and it appears that the revised claim is a structure/function claim under U.S.C. 343(r)(6) and 21 CFR 101.93.

In your letter you also asked FDA to comment on whether the statement "Alpha-Lipoic Acid helps maintain normal blood sugar balance in the body" would be an appropriate structure/function claim under 21 U.S.C. 343(r)(6). In the preamble to the January 6, 2000 final rule (see 65 FR 1000), FDA stated that health maintenance claims that do not imply disease treatment or prevention would be acceptable structure function claims. We stated that if the health maintenance claim did not use terms that are so closely identified with a specific disease or that so clearly referred to a particular at-risk population, FDA believed that such a claim could be a structure/function claim under 21 U.S.C. 343(r)(6) (see discussion at 65 FR 1018). In that your proposed claim does not appear to imply treating, preventing, or mitigating abnormalities in the regulation of blood sugar, it does not appear to be a disease claim.

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But, we wish to note out that our comments on the two claims you inquired about are based solely on the information contained in your letter. As we discussed in the preamble to the final rule, the context in which a particular claim is made is important in determining whether a claim may be a disease claim or a structure/function claim. Consequently, although the two claims contained in your letter appear to be structure/function claims under 21 U.S.C. 343(r)(6), whether that is the case depends upon, in part, other representations that you may be making in your labeling that affect the meaning of the aforementioned claims.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Chicago District Office, Compliance Branch, HFR-MW140

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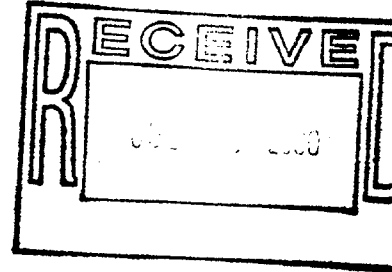
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:7/25/00:71642.adv:disc48



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July 17, 2000

Mr. John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling, and
Dietary Supplements
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Mr. Foret:

This is in response to your June 13, 2000 letter responding to our notification of statements in labeling pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. In your letter, you stated that the claim, "In animal models that mimic women's post-menopausal years, studies by Arjmandi and colleagues have demonstrated that a diet containing Isoflavones within soy helped maintain bone density" suggests that soy isoflavones are intended to treat, prevent or mitigate a disease, namely osteoporosis.

We respectfully request clarification as to whether substitution of the word "health" for the word "density" in the above claim would sufficiently alter the statement so that it would be an appropriate structure/function claim consistent with the requirements of section 403(r)(6) of the Act.

We additionally request clarification as to whether the claim, "Alpha-Lipoic Acid helps maintain normal blood sugar balance in the body" would be an appropriate structure/function claim consistent with section 403(r)(6), and whether it is distinguishable from the structure/function claim set forth in the January 6, 2000 Final Rule, "Use as part of your diet to help maintain a healthy blood sugar level."

Sincerely,

Richard Staack, Ph.D.
Senior Scientist
Cognis Nutrition & Health

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